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PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	Lixiao Wang
Application No.:	08/685338
Filed:	July 23, 1996
For:	High Compliance, High Strength Catheter Balloons Useful
Examiner:	for Treatment of Gastrointestinal Lesions
Group Art Unit:	Cris Loiren Rodriguez 3763

Mail Stop Amendment  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Docket No.:  
S63.2B-5902-US01

DECLARATION OF JEFFREY BRUCE

Jeffrey Bruce states:

1. I am Global Product Manager, Dilation, for Boston Scientific Corporation's gastrointestinal products.
2. Accompanying this Declaration is a document entitled Supplement to Jeffrey Bruce Declaration that contains confidential business information of Boston Scientific Corporation that is exempt from FOIA Disclosure, (FOIA exemption 4 (5 U.S.C. 552(b)(4)). On that document is a table showing Boston Scientific's calculation of the US GI procedures performed for the years 1998-2003, broken down to separate balloon procedures from rigid procedures, and then for the same years, the penetration of the balloon procedures all the C-R-E™ balloon products and the for all of the C-R-E™ balloon products except the 18-20 mm balloon catheters. The information in that document, and my marketing experience in this product market, provides the basis for the statements provided herein.
3. Boston Scientific sells balloon catheters designed for use in the gastrointestinal (GI) and the pulmonary systems. My responsibilities pertain specifically to GI sales (i.e. products for both esophageal and alimentary tracts).

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4. In GI system procedures, dilatations frequently require expansions of greater than 1 mm. A specific balloon catheter competes for these procedures with other balloon catheters and with rigid dilators or bougies. Many of the balloon catheters sold for GI procedures have PET balloons that expand to a single size. With such single size balloons, practitioners frequently have to use multiple catheters to properly dilotate a GI lesion.
5. In 1998 Boston Scientific Corporation introduced a line of catheters for these procedures under the trademark C•R•E™. The C•R•E™ balloons are designed for delivery, inflation, deflation and retraction through a typical endoscope lumen. A particular feature of the C•R•E™ balloon catheters is that they are marketed as having three different dimensions at three different inflation pressures. In all cases the initial diameter is specified at an inflation pressure of 3 atm. An intermediate pressure is then specified at which the balloon will be at a second diameter, 1-1.5 mm larger than the initial diameter. At the final pressure specified for the balloon the balloon has again increased by the same increment of diameter. The product line offers balloons in size ranges from 6/7/8 mm to 18/19/20 mm.
6. The C•R•E™ GI line has been has been very successful commercially. Boston Scientific tracks the total number of procedures for GI dilatation done each year and the relative numbers for balloon procedures and rigid procedures within that market. Since 1998 the number of balloon procedures has increased and the fraction represented by the C•R•E™ balloon catheters has grown to become a large majority of those procedures. This success is in large part due to the fact that the product line substantially simplifies many GI dilatation procedures and that the multi size feature is available in a wide range of sizes.
7. I am informed that, for purposes of the patent application identified above, the largest balloon (18-20 mm range) is not exemplary of the pertinent invention. Omitting the catheters using that balloon from my calculation, I find that products of the invention still have captured nearly  $\frac{1}{2}$  the total balloon dilatation market in GI procedures. Moreover, in my opinion, if

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Boston Scientific only had the one largest balloon in the C•R•E™ product line, that balloon's sales would almost certainly have been substantially less. Some of the sales of each of the C•R•E™ result from our ability to provide a whole line of size ranges to the practitioner.

8. To date, competitors in the GI balloon market have not been able to replicate the technology that enables one balloon to achieve three distinct sizes. This is one of the competitive advantages of the C•R•E™ balloons. There are two competitors in the US marketplace that offer PET balloons, Cook Medical and C.R. Bard. These technologies, to date, have not had much impact on Boston Scientific Corporation's sales of C•R•E™ balloons.

9. The undersigned being hereby warned that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any resulting registration, declares all statements made of my own knowledge are true and all statements made on information and belief are believed to be true.

11/5/04  
Date

Jeffrey D. Bruce  
Jeffrey Bruce